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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/688,276	10/20/2003	Masaru Kato	049441-0133	3781

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EXAMINER	
CHOWDHURY, IQBAL HOSSAIN	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 07/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/688,276	KATO ET AL.	
	Examiner	Art Unit	
	Iqbal Chowdhury, Ph.D.	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-37,125 and 129* is/are pending in the application.

4a) Of the above claim(s) *36-37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-35,125 and 129* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/03, 03/04, 1/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This application is a continuation of U.S. Application Serial No. 09/695,423 filed on October 25. 2000, which is a continuation of U.S. Application Serial No. 09/298,924 filed on April 26. 1999, which is a divisional of U.S. Application Serial No. 08/750,569 filed on February 24. 1997, which is the National Stage of International Application No. PCT/JP95/01189, filed on June 14. 1995.

The preliminary amendment filed on 4/21/2006 amending claims 25-37, and 125, canceling claims 123-124 and 126-128, and newly adding claim 129 is acknowledged.

Claims 25-37, 125 and 129 are pending.

Applicant's election with traverse of Group III, Claims 25-32, 33, 34, 123 and 125-128 in the response filed on 4/21/2006 is acknowledged.

The traversal is on the ground(s) of "separate and distinct premise of the restriction requirement i.e. sharing of several claims by all the identified claim groups. Applicants argue that The MANUAL OF PATENT EXAMINING PROCEDURE, § 809.02 and 809.3, requires that the PTO, in the context of a restriction requirement, identify any linking (generic) claims, i.e. claim 25, which is overlapping among Groups I-IV. Furthermore, a restriction requirement in this circumstance is conditional on the non-allowance of the linking claims. Thus, it is typical PTO practice to require an applicant to elect a species to which the claims are restricted if no linking claim is found to be allowable. In an effort to clarify the situation and to facilitate prosecution, applicants have combined the foregoing traversal with a revision of the claims, whereby sole independent claim 25 incorporates certain structural (sequence) recitations from

claims 123 and 124, now cancelled. Accordingly, the streamlined claim set, as revised, includes linking claim 25 that prescribes a Markush group of separate amino acid-sequence species. Applicants further submit to consider imposing a species election requirement, with the understanding that, upon a determination of patentability as to the elected species, office would examine a reasonable number of additional species. MPEP §809.02 (Aug. 2001).

Applicant's arguments have been fully considered but are not deemed persuasive to overcome the restriction requirement for the following reason:

The elected Group III comprises two different amylase enzymes as set out in SEQ ID NO: 6 and in SEQ ID NO: 8, which are derived from two different species such as Sulfolobus solfataricus and Sulfolobus acidocaldarius i.e. two enzymes are chemically, structurally and functionally different as well as independent and distinct. The two enzymes are two distinct products. The practice of USPTO is to provide one patent for one product (invention). In addition, Claim 25 apparently looks like generic claim because applicants put two different inventions in one claim, which is contrary to the USPTO practice. A search for each of the sequences would not be done solely by searching electronic sequence databases as such databases seldom provide extensive coverage of all variants which are known or have been made of a single protein such that word searching for each variant is required. Such searching would likely be different for each variant as each change may have distinct effects. Furthermore, even sequence searching of the two different sequence or variants would be a substantial burden on the office as each sequence has to be examined individually to determine if it includes variants and reference teaching one such sequence or variants would neither anticipate nor make obvious any of the other three. As such the novelty and non-obviousness of each sequence or variants

would have to be addressed individually creating a large burden on the office. As restriction is clearly permissible even among related inventions as defined in MPEP 808 and 35 U.S.C. 121 allows restriction of inventions, which are independent or distinct. Thus these inventions are distinct for the reasons given above and explained previously.

"*For purposes of the initial requirement, a serious burden on the examiner may be prima facie shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search as defined in MPEP 808.02.*" (see MPEP 803).

After further consideration, the examiner finds that claim 35 to be included in Group III.

The requirement is still deemed proper and is therefore made **FINAL.**

Claims 36-37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in communication filed on 4/21/2006.

Claims 25-32, 33, 34, 35, 125 and 129 will be examined herein.

Priority

Acknowledgement is made of applicants claim for priority of U.S. Application Serial No. 09/695.423 filed on October 25. 2000, which is a continuation of U.S. Application Serial No. 09/298.924 filed on April 26. 1999, which is a divisional of U.S. Application Serial No. 08/750.569 filed on February 24. 1997, which is the National Stage of International Application No. PCT/JP95/01189, filed on June 14. 1995.

Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:
(1) if a machine or apparatus, its organization and operation;
(2) if an article, its method of making;
(3) if a chemical compound, its identity and use;
(4) if a mixture, its ingredients;
(5) if a process, the steps.

In this case abstract is too long i.e. abstract has 193 words, which is beyond the upper limit of the abstract requirement of the specification. Appropriate corrections are required.

The title of the invention is not descriptive. A new title is required that is clearly

indicative of the invention to which the claims are directed.

The following title is suggested: "A novel amylase, process for producing the enzyme, use thereof, and gene coding for the same".

Claim Objections

Claims 25-34, 125 and 129 are objected to as encompassing non-elected subject matter. Appropriate correction is required.

Claim 26 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 28. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 25-32, 33, 34, 125 and 129 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

In the absence of the hand of man, naturally occurring nucleic acids and /or proteins are considered non-statutory subject matter. *Diamond and Chakrabarty*, 206 USPQ 193 (1980). This rejection may be overcome by amending the claims to contain wording such as "An isolated and purified protein". For examination purpose the claim is read as such.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 25-35 and 125 and 129 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite and vague for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 25 is indefinite in the recitation of the "an equivalent thereof" with reference to amylase, which is confusing. Does the term "an equivalent" refer to a structural equivalent or functional equivalent of amylase? If structural equivalent, does it mean mutants or variants of amylase of SEQ ID NO: 6? If functional equivalent, does it mean the same activities of wild type amylase or something else. Clarification is required. For examination purpose examiner will interpret it as any protein having amylase activity.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 25-29, 31-35, 125 and 129 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These claims are directed to a genus of a variant of amylase which is isolated from an archaebacterium belonging to genus Sulfolobus and which acts on a substrate saccharide composed of at least three sugar units wherein at least three sugar units from the reducing end are glucose residues so as to liberate principally monosaccharides and/or disaccharides by

hydrolyzing the substrate saccharide from the reducing end side. Claim 26 recites the amylase which has a principal activity of acting on a substrate saccharide, the substrate saccharide being composed of at least three sugar units wherein at least three sugar units from the reducing end side are glucose residues and the linkage between the first and the second glucose residues from the reducing end side is α-1, α-1 while the linkage between the second and the third glucose residues from the reducing end side is α-1,4 so as to liberate α,α-trehalose by hydrolyzing the α1,4 linkage between the second and the third glucose residues and claim 27 recites that the amylase, wherein said amylase also has an activity of endotype-hydrolyzing one or more α1,4 linkage linkages within the molecular chain of a substrate. Claim 28 recites that the amylase, wherein said amylase has an activity of hydrolyzing a substrate trehalose-oligosaccharide such as glucosyltrehalose and maltooligosyl-trehalose at the α-1,4 linkage between the second and the third glucose residues from the reducing end side to liberate α,α-trehalose. Claim 29 recites that the amylase, wherein its molecular weight measured by SDS-polyacrylamide gel electrophoresis is 61,000 to 64,000, approximately. Claim 31 recites that the amylase has the isoelectric point is pH 4.3 to pH 5.4. Claim 32 recites that the amylase activity can be fully inhibited with 5 mM CuSO4 and claim 33 and 34 recite that the amylase is derived from an archaebacterium belonging to the order Sulfolobales and genus Sulfolobus. Claim 35 recites that the amylase derived from the strain Sulfolobus solfataricus strain KM1 (FERM BP-4626). Claim 125 recites that the polypeptide further comprises Met at the N terminus and Claim 129 recites that the substrate of the amylase is at least one of glucosyltrehalose and maltooligosyl trehalose. As discussed in the written description guidelines the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by

actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. A representative number of species means that the species, which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

The specification teaches the structure of only two representative species of such proteins. Moreover, the specification fails to describe any other representative species by any identifying characteristics other than the functionality of encoding an amylase polypeptide. While Claims 29, 31 and 32 add some additional identifying characteristics such as molecular weight, isoelectric point, and inhibition of the amylase activity by copper sulfate, to the limitations of the genus, none of these characteristics, by itself is sufficient to change the fact that the claims include proteins which are highly variable in both structure and function. As even small changes in structure can change any one of the listed properties, inclusion of all of these characteristics together leads one to a conclusion that the recited genus is highly variable in structural or functional characteristics. Thus for all the reasons discussed, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Claims 25-35, 125 and 129 are rejected under 35 U.S.C. 112, first paragraph, because the

specification, while being enabling for an enzyme with SEQ ID NO: 6 which is isolated from an archaebacterium belonging to genus Sulfolobus and which acts on a substrate saccharide composed of at least three sugar units wherein at least three sugar units from the reducing end are glucose residues so as to liberate principally monosaccharides and/or disaccharides by hydrolyzing the substrate saccharide from the reducing end side, does not reasonably provide enablement for any or all variants of such polypeptides. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Claim 25 is so broad as to encompass any or all variants of such polypeptides from any source which acts on a substrate saccharide composed of at least three sugar units wherein at least three sugar units from the reducing end are glucose residues so as to liberate principally monosaccharides and/or disaccharides by hydrolyzing the substrate saccharide from the reducing end side. Claim 26 recites the amylase which has a principal activity of acting on a substrate saccharide, the substrate saccharide being composed of at least three sugar units wherein at least three sugar units from the reducing end side are glucose residues and the linkage between the first and the second glucose residues from the reducing end side is α-1, α-1 while the linkage between the second and the third glucose residues from the reducing end side is α-1,4 so as to liberate α,α-trehalose by hydrolyzing the α1,4 linkage between the second and the third glucose residues and claim 27 recites that the amylase, wherein said amylase also has an activity of endotype-hydrolyzing one or more α1,4 linkage linkages within the molecular chain of a substrate. Claim 28 recites that the amylase, wherein said amylase has an activity of hydrolyzing a substrate trehalose-oligosaccharide such as glucosyltrehalose and maltooligosyl-trehalose at the

α-1,4 linkage between the second and the third glucose residues from the reducing end side to liberate α,α-trehalose. Claim 29 recites that the amylase, wherein its molecular weight measured by SDS-polyacrylamide gel electrophoresis is 61,000 to 64,000, approximately. Claim 30 recites that the amylase has the following physical and chemical properties: (1) Optimum pH with in the range from 4.5 to 5.5; (2) Optimum temperature within the range from 60 to 85 degree C.; (3) pH Stability within the range from 4.0 to 10.0; and (4) Thermostability which allow 100% enzymatic activity to remain even after exposure at 80 degree C for 6 hours. Claim 31 recites that the amylase has the isoelectric point is pH 4.3 to pH 5.4. Claim 32 recites that the amylase activity can be fully inhibited with 5 mM CuSO4 and claim 33 and 34 recite that the amylase is derived from an archaebacterium belonging to the order Sulfolobales and genus Sulfolobus. Claim 35 recites that the amylase derived from the strain Sulfolobus solfataricus strain KM1 (FERM BP-4626). The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of amylase broadly encompassed by the claims. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to the nucleotide and encoded amino acid sequence of only two amylase.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims,

and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple point mutations or substitutions.

The specification does not support the broad scope of the claims which encompass any or all variants polypeptide from any source which acts on a substrate saccharide composed of at least three sugar units because the specification does **not** establish: (A) regions of the protein structure which may be modified without effecting amylase activity; (B) the general tolerance of amylase to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any amylase residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

The specification does not support the broad scope of the claims which encompass any or all variants of polypeptide having amylase activity wherein the amylase has optimum temperature within the range of 60-80 degrees C and optimum pH stability within the range of pH 4.0-10.0 because the specification does **not** establish: (A) a region of the protein which may be modified without effecting thermal stability, pH stability and amylase activity; (B) the general tolerance of amylase to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any amino acids with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any polypeptide from any source which, acts on a substrate saccharide composed of at least three sugar units. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of any amylase having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 25-35, 125 and 129 are rejected under 35 U.S.C. 102(b) as being anticipated by Lama et al. (Biotechnology Forum. Eur., 1991, Vol. 8(4): 201-203, see IDS). Claims 25-35, 125 and 129 of the instant application is drawn to an amylase which acts on a substrate saccharide composed of at least three sugar units wherein the last three sugar units from the reducing end are glucose residues so as to liberate principally monosaccharides and/or disaccharides by hydrolyzing the substrate from the reducing end side and the linkage between the first and the second glucose residues from the reducing end side is α-1, α-1 while the linkage between the second and the third glucose residues from the reducing end side is α-1,4 so as to liberate α, α-

trehalose by hydrolyzing the α-1,4 linkage between the second and the third glucose residues, wherein the molecular weight of the enzyme is between 61,000 to 64,000, wherein the enzyme has an optimum pH range of pH 4.5-5.5, temperature range of 60-85 ° C and a pH stability in the range of pH 4.0 to 10.0 and a thermostability of 100% (activity) even after exposure at 80 ° C for 6 hours, an isoelectric point of pH 4.3 to 5.4, wherein the enzyme is inhibited by 5 mM of Cu salt and wherein the enzyme is derived from a bacteria belonging to *Sulfolobales*, belonging to the genus S. solfataricus or its variants and wherein the polypeptide of the enzyme comprises SEQ ID NO:6 or 8 or an equivalent sequence thereof, wherein the polypeptide comprises a methionine at the N-terminus and has an optimum temperature between 60 to 85 ° C. Lama et al. disclose an identical preparation of the enzyme isolated from the very same source i.e., S.solfataricus which could be a variant of the bacterial strains that applicants have claimed or an equivalent of the polypeptide with SEQ ID NO: 6 or 8. Lama et al. describe an enzyme which acts on a substrate saccharide composed of at least three sugar units wherein the last three sugar units from the reducing end are glucose residues so as to liberate principally monosaccharides and/or disaccharides by hydrolyzing the substrate from the reducing end side and the linkage between the first and the second glucose residues from the reducing end side is α-1, α-1 while the linkage between the second and the third glucose residues from the reducing end side is α-1,4 so as to liberate α, α-trehalose by hydrolyzing the α-1,4 linkage between the second and the third glucose residues. Lama et al. also describe the enzyme as a thermophilic enzyme wherein the enzyme has an optimum pH between pH 4.5-5.5, temperature range of 60-85 ° C and pH stability in the range of pH 4.0 to 10.0 and a thermostability of 100% (activity) even after exposure at 80 ° C for more than 5 hours. The reference does not teach explicitly the isoelectric point of the

enzyme as pH 4.3 to 5.4 or that the enzyme is inhibited by 5 mM of CuSO4. However, judging from all the other similarities between the enzyme of the reference and the enzyme claimed in the instant application, such characteristics including the amino acid sequence (SEQ ID NO: 6 or 8) would be inherent characteristics of the said enzyme. Lama et al. do teach that the enzyme is inhibited by 4 mM of CuCl2 or using substrate glucosyltrehalose and maltooligosyl trehalose. Therefore Lama et al. anticipate claims 25-35, 125 and 129 of this application as written.

In response to the above rejection applicants may argue that the reference provided by the examiner does not provide support for all the limitations claimed. However, such an argument would not be persuasive to overcome the rejection because, first of all, applicants have included the bacterial strains and equivalents of the enzyme. Secondly, characteristics such as amino acid sequence, a methionine being in the N-terminal of the enzyme, isoelectric point, mol.wt. etc. are all inherent characteristics of the enzyme and none of these characteristics have been imparted to the enzyme by the applicants. Furthermore, the decisions handed down in *In re Bell* and *In re Deuel* does not apply since applicants are claiming polypeptides and not polynucleotides. Lastly, since the Office does not have the facilities for examining and comparing applicants' protein with the protein of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same material structural and functional characteristics of the claimed protein). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine

grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 25-32, 33-35, 125 and 129 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 25-34 and 151 of U.S. Application 09/695,423. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

Claims 25-32, 33, 34, 35, 125 and 129 of the instant application is directed to an amylase protein that comprises an amino acid sequence of SEO ID NO: 6 and an equivalent thereof, wherein said

amylase acts on a substrate saccharide, the substrate saccharide being composed of at least three sugar units wherein at least three sugar units from the reducing end are glucose residues, so as to liberate principally monosaccharides and/or disaccharides by hydrolyzing the substrate saccharide from the reducing end side (claim 25).

Claim 26 recites that the amylase claimed in Claim 25, which has a principal activity of acting on a substrate saccharide, wherein the substrate saccharide is composed of at least three sugar units, wherein at least three sugar units from the reducing end side are glucose residues, and wherein the linkage between the first and the second glucose residues from the reducing end side is α-1, α-l while the linkage between the second and the third glucose residues from the reducing end side is α-1,4 such that said amylase liberates α,α-trehalose by hydrolyzing the α-1,4 linkage between the second and the third glucose residues.

Claim 27 recites that the amylase claimed in Claim 25, wherein said amylase also has an activity of endotype-hydrolyzing one or more α-1,4 linkages within the molecular chain of a substrate.

Claim 28 recites that the amylase claimed in Claim 25, wherein said amylase has an activity of hydrolyzing a substrate trehalose oligosaccharide at the a-1,4 linkage between the second and the third glucose residues from the reducing end side to liberate α,α-trehalose.

Claim 29 recites that the amylase claimed in Claim 25, wherein its molecular weight measured by SDS-polyacrylamide gel electrophoresis is 61,000 to 64,000.

Claim 30 recites that the amylase claimed in Claim 25, wherein the amylase has the following physical and chemical properties:

(1) Optimum pH with in the range from 4.5 to 5.5;

(2) Optimum temperature within the range from 60 to 85oC;

(3) pH stability within the range from 4.0 to 10.0; and

(4) Thermostability, which allow 100% enzymatic activity to remain even after exposure at 80oC for 6 hours.

Claim 31 recites that the amylase claimed in Claim 25, wherein the isoelectric point measured by isoelectric focusing is PH 4.3 to pH 5.4.

Claim 32 recites that the amylase claimed in Claim 25, wherein its activity can be fully inhibited with 5 mM CuSO4.

Claim 33 recites that the amylase claimed in Claim 25, wherein the amylase is derived from an archaebacterium belonging to the order Sulfolobales.

Claim 34 recites that the amylase claimed in Claim 33, wherein the amylase is derived from an archaebacterium belonging to the genus Sulfolobus.

Claim 35 recites that the amylase claimed in claim 34, wherein the archaebacterium belonging to the genus Sulfolobus is the Sulfolobus solfataricus strain KM1 (FERM BP-4626).

Claim 125 recites that the polypeptide further comprises Met at the N terminus.

Claim 129 recites that the amylase claimed in Claim 28, wherein the substrate is at least one of glucosyltrehalose and maltooligosyl trehalose.

Claim 25 of U.S. Application 09/695,423 recites that an amylase which acts on a substrate saccharide, the substrate saccharide being composed of at least three sugar units wherein at least three sugar units from the reducing end are glucose residues, so as to liberate principally monosaccharides and/or disaccharides by hydrolyzing the substrate saccharide from the reducing end side, and shows a trehalose oligosaccharide-hydrolyzing activity of more than

10.6 units/mg wherein 1 unit equals the activity of liberating 1 umol of α,α-trehalose per hour from maltotriosyl trehalose.

Claim 26 recites that the amylase claimed in Claim 25 which has a principal activity of acting on a substrate saccharide, the substrate saccharide being composed of at least three sugar units wherein at least three sugar units from the reducing end side are glucose residues and the linkage between the first and the second glucose residues from the reducing end side is α-1, α-1 while the linkage between the second and the third glucose residues from the reducing end side is α-1,4, so as to liberate α,α-trehalose by hydrolyzing the α-1,4 linkage between the second and the third glucose residues.

Claim 27 recites that the amylase claimed in Claim 25, wherein said amylase also has an activity of endotype-hydrolyzing one or more α-1,4 linkages within the molecular chain of a substrate.

Claim 28 recites that the amylase claimed in Claim 25, wherein said amylase has an activity of hydrolyzing a substrate trehalose oligosaccharide at the α-1,4 linkage between the second and the third glucose residues from the reducing end side to liberate α,α-trehalose.

Claim 29 recites that the amylase claimed in Claim 25, wherein its molecular weight measured by SDS-polyacrylamide gel electrophoresis is 61,000 to 64,000, approximately.

Claim 30 recites that the amylase claimed in Claim 25, wherein the amylase has the following physical and chemical properties:

(1) Optimum pH with in the range from 4.5 to 5.5;

(2) Optimum temperature within the range from 60 to 85oC;

(3) pH Stability within the range from 3.0 to 13.0; and

(4) Thermostability, which allow 100% enzymatic activity to remain even after exposure at 80 to 85oC for 6 hours.

Claim 31 recites that the amylase claimed in Claim 25, wherein the isoelectric point measured by isoelectric focusing is pH 4.3 to pH 5.4.

Claim 32 recites that the amylase claimed in Claim 25, wherein its activity can be fully inhibited with 5 mM CuSO4.

Claim 33 recites that the amylase claimed in Claim 25, wherein the amylase is derived from an archaebacterium belonging to the order Sulfolobales.

Claim 34 recites that the amylase claimed in Claim 33, wherein the amylase is derived from an archaebacterium belonging to the genus Sulfolobus.

Claim 35 recites that the amylase claimed in Claim 34, wherein the archaebacterium belonging to the genus Sulfolobus is the Sulfolobus solfataricus strain KM1 (FERM BP-4626).

Claim 151 recites that the amylase claimed in Claim 28 wherein said trehalose oligosaccharide is glucosyltrehalose or maltooligosyl trehalose.

Therefore, claims 25-35, and 151 of copending U.S. Application 09/695,423 anticipates claims 25-35, and 129 of the instant application because these claims are fully within the scope of claims 25-35, and 129 of the instant application, although the conflicting claims are not identical, they are not patentably distinct from each other.

Regarding claim 125 of the instant application, that recites "... said amino acid sequence further comprises Met at the N-terminus", which is being obvious over the copending U.S. Application 09/695,423, since the copending application also teach a sequence which is 100%

identical to SEQ ID NO: 2 of the instant application. Copending application does not teach putting a Met residue at the N-terminus of SEQ ID NO: 2.

It would have been obvious to one of ordinary skill in the art at the time of the invention was made to put a Met residue (initiation codon) at the N-terminus of SEQ ID NO: 2 to express the protein to be used for hydrolyzing saccharide so as to liberate principally monosaccharides and/or disaccharides from the reducing end side as taught by copending application.

Conclusion

Status of the claims:

Claims 25-32, 33, 34, 35, 125 and 129 are pending.

Claims 25-32, 33, 34, 35, 125 and 129 are rejected.

No claim is in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Iqbal Chowdhury whose telephone number is 571-272-8137. The examiner can normally be reached on 9:00-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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